Remarks

The sole remaining issue in the present application is the rejection of claims 1-8, 10-15, and 18-19 under 35 U.S.C. §§ 101 and 112, first paragraph, for lack of utility. The Examiner has stated in the Office Action and the Advisory Action that Applicants' previously submitted arguments and the Declaration of Dr. Patturajan ("the Patturajan Declaration") were insufficient to overcome the rejection of claim 1-8 and 10-15. Applicants traverse the rejection of the pending claims for at least the following reasons.

SEC1/FGF has a substantial and specific utility as a member of the FGF family of polypeptide growth factors

The Applicants have demonstrated that SEC1/FGF is a FGF growth factor. The instant specification describes SEC1/FGF, a polypeptide that is 100% identical to human FGF-22 precursor over the length of the molecule. (*See,* SEQ ID NO: 2 at pages 12-13, and GenBank Accession Number NP_065688). The specification also describes how the SEC1/FGF polypeptide is 54% identical to a known, related FGF protein, human FGF10 precursor ("hFGF10"). (*See,* pages 10-11 and GenBank Accession Number O15520). Moreover, SEC1/FGF has a molecular weight of 19.662 kDa (as determined by molecular weight calculation tools known to those skilled in the art). It is known that FGF polypeptides generally have molecular weights generally in the range of from 17 to 34 kDa. (*See,* Orintz and Itoh, 2001. Genome Biology 2(3): 3005.1-3005.12, courtesy copy enclosed).

Detailed analysis of SEC1/FGF and FGF-10 reveals that these two FGFs, along with the closely related polypeptide FGF-7, comprise a unique subfamily of FGF polypeptides. (*See,* Appendix I). This analysis was performed using the methods of Ornitz and Itoh. (*See,* Orintz and Itoh, 2001. Genome Biology 2(3): 3005.1-3005.12). Further, SEC1/FGF and hFGF10 also contain similar FGF domain structures. (*See,* http://www.sanger.ac.uk/cgi-bin/Pfam/complexes.pl?acc=PF00167 and http://www.expasy.org/cgi-bin/niceprot.pl?Q9HCT0). Moreover, Applicants have demonstrated herein that SEC1/FGF and hFGF10 interact with the same FGF receptor FGFR2 IIIb (*See,* Appendix II). Likewise, Applicants also note that the Patturajan Declaration presented in the response filed August 8, 2003, further demonstrates the receptor specificity of SEC1/FGF.

In the Office action mailed October 30, 2003 (Paper No. 11), the Examiner contended that "the biological activities similar to known human FGFs is not substantial in the absence of supporting evidence." (*See,* Office action, page 3). Applicants traverse.

The FGF subfamily containing SEC1/FGF, FGF-10, and FGF-7 have substantial and specific utilities in regulating inflammatory disorders and stimulating vascular cell and epithelial cell motility and differentiation. Functionally, the FGF subfamily containing FGF-7 (also described as keratinocyte growth factor-1 or KGF-1), FGF-10 (also described as KGF-2) and FGF-22, which, as stated above, is 100% identical to the SEC1/FGF polypeptide of the instant invention, has been shown to be involved in inflammatory disorders. For example, WO98/16642, cited in and incorporated by reference in the as-filed specification, demonstrates the ability of an FGF-10 polypeptide to stimulate epithelial cell proliferation. (*See*, Specification, page 11, line 2). Furthermore, WO96/25422 (described in WO98/16642) teaches the use of FGF-10 in cell growth stimulation and proliferation for angiogenesis, prevention of hair loss, healing of dermal wounds and the differentiation of muscle cells, nervous tissue, prostate cells and lung cells. In addition, FGF-7 induction has been demonstrated to occur the dermis during wound healing (*See*, Werner *et al.*, PNAS 1992, 89:6896-6900, courtesy copy enclosed). One skilled in the art would readily recognize the similarities between FGF-10, FGF-7 and FGF-22, as these have been emphasized in the instant specification. Moreover, the Patturajan Declaration further describes the functional similarity (including the impact of FGF on the proliferation of epithelial cells) and the receptor specificity of this FGF-subfamily, which includes FGF-7, FGF-10 and FGF-22. At the time of the application, the inventors recognized that SEC1/FGF was similar to closely related family members FGF-10 and FGF-7 in both receptor specificity and structural similarity. As noted in the Utility Examination Guidelines, "when a class of proteins is defined such that the members share a specific, substantial, and credible utility, the reasonable assignment of a new protein to the class of sufficiently conserved proteins would impute the same specific, substantial and credible utility to the assigned protein." (*See*, Fed. Reg., Vol. 66. No. 4, January 5, 2001, p. 1096). Therefore, as FGF-7 and FGF-10 were well characterized at the time of filing, Applicants contend that it is reasonable to assign similar utility for SEC1/FGF based on the homology and structural similarity between SEC1/FGF and FGF-7/ FGF-10.

Therefore, Applicants have demonstrated that SEC1/FGF is an FGF growth factor and that FGF growth factors in the FGF-10/FGF-7 subfamily have patentable utility in regulating inflammatory disorders, in addition to stimulating vascular cell and epithelial cell motility and differentiation. Thus, Applicants assert that as SEC1/FGF has a substantial and specific utility, this rejection should be withdrawn.

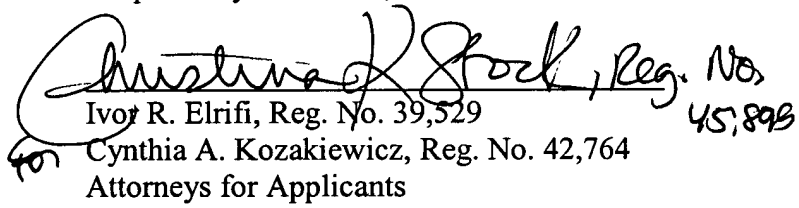
The 35 USC § 112, first paragraph rejections

Claims 1-8, 10-15, and 18-19 are rejected under 35 U.S.C. § 112, first paragraph, for not being supported by either a specific and substantial asserted utility or a well established utility. Applicants have demonstrated above that claims 1-8, 10-15, and 18-19 are supported by a specific, substantial, and credible utility. Therefore, this rejection should be withdrawn.

CONCLUSION

On the basis of the foregoing amendments and remarks, Applicants respectfully submit that this paper is fully responsive and that the pending claims are in condition for allowance. Such action is respectfully requested. If there are any questions regarding these amendments and remarks, the Examiner is encouraged to contact the undersigned at the telephone number provided below.

Respectfully submitted,



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